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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,996	03/17/2004	Michael M. Meguid	RFSUNY-3673 R1410	4408
7590 01/11/2006			EXAMINER	
Sander Rabin MD JD Convergent Technology Patent Law Group Whiteman Osterman & Hanna, LLP One Commerce Plaza Albany, NY 12260			HAMA, JOANNE	
			ART UNIT	PAPER NUMBER
			1632	
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Please find below and/or attached an Office communication concerning this application or proceeding.



### **DETAILED ACTION**

Applicant filed responses to the Non-Final Office Action of March 14, 2005 on June 28, 2005 and October 14, 2005. Claims 9-23 are withdrawn from consideration, following a Restriction Requirement, March 14, 2005. Claims 1-8 are under consideration.

#### **Withdrawn Rejections**

##### **35 U.S.C. § 101**

Applicant's arguments, see page 6 of Applicant's response, filed June 28, 2005, with respect to the rejection of claims 1-3, 5-7 under 35 U.S.C. § 101 have been fully considered and are persuasive. Applicant has amended the claims. The rejection of claims 1-3, 5-7 has been withdrawn.

##### **35 U.S.C. § 102(a)**

Applicant's arguments, see page 14 of Applicant's response, filed June 28, 2005, with respect to the rejection of claims 1, 2, 4, 5, 7, 8 have been fully considered and are persuasive. Applicant has provided a declaration indicating that Dr. Meguid is sole inventor of the claimed invention, who conceived the idea of the claimed invention in spring, 1999 (Applicant's declaration, page 1). The rejection of claims 1, 2, 4, 5, 7, 8 has been withdrawn.

##### **35 U.S.C. § 103(a)**

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Applicant's arguments, see pages 17-20 of Applicant's response, filed June 28, 2005, with respect to the rejection of claims 1-3, 5, 7 have been fully considered and are persuasive. Applicant indicates that Inui does not provide motivation for an artisan to practice the claimed invention using bariatric surgeries. The rejection of claims 1-3, 5, 7 has been withdrawn.

**Maintained Rejections**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-7 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

non-human mammals having a gastrointestinal system, wherein surgery reduced the volume and digestive area of the gastrointestinal tract and results in permanent reduction of preoperative weight,

does not reasonably provide enablement for

any non-mammalian animals, any transgenic, genetically-modified, or cloned animals having a gastrointestinal system, wherein surgery reduces the volume and digestive are of the gastrointestinal tract and results in permanent reduction of preoperative weight.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons or record, March 14, 2005.

The Applicant addresses the Examiner's concern of what steps a skilled artisan would need to carry out to ensure survival of the animal (Applicant's response, page 8-10). Regarding this issue, the Examiner finds the Applicant's argument persuasive and finds surgical survival to be enabled.

Regarding the issue that the Applicant does not reasonably provide enablement for "any transgenic, genetically-modified, or cloned (non-human mammalian) animals, the Examiner maintains the rejection. The Applicant indicates that the Examiner misunderstood the import and scope of the Applicant's claims (Applicant's response, pages 10-11) because the extant transgenic, cloned, or genetically modified non-human animals are candidates for the surgery and the claims are drawn to the resultant transgenic, cloned, or genetically modified nonhuman animals emerging from the surgery. However, the Examiner disagrees with the Applicant's argument because in order for an artisan to arrive at the claimed invention (i.e. the surgically modified animal), an artisan would need to know how to make the candidate animals that are used in the invention. It is understood that a non-human mammalian model for obesity is one model an artisan would use in the claimed invention. However, with regards to making these animal candidates, an artisan would need to know how to make these transgenic animals. That is, an artisan would need guidance as to what transgene constructs to use (e.g. promoters, nucleic acid sequence that encodes a protein of

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interest) and what phenotype the transgenic animal is to exhibit. As indicated in the Office Action of March 14, 2005, pages 6-7, making transgenic animals, in general, are unpredictable because there is no way of predicting what transgene constructs have activity in the animal. As such, the claims broadly encompass any transgenic non-human animal model, and neither the specification nor the art provide guidance for an artisan to practice the claimed invention such that an artisan could reliably obtain the transgenic animals used as the starting material in the claimed invention. For this reason, the claims remain rejected. Similarly, with regards to the claimed invention encompassing cloned non-human mammalian animals, Westhusin et al. has indicated that cattle, sheep, goat, mice, and pigs have been cloned, however, neither the specification nor the art has provided guidance as to how to create any and all cloned non-human mammalian animals encompassed by the claims. For this reason, the claimed invention remains rejected.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 remain rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.

Claim 1 remains rejected with regards to the use of the words, "substantially" and "normal." While the Applicant has referred to Examiner to the specification to indicate what is meant by "normal," the problem with using "normal" is that it is not clear what metes and bounds are used to describe the other different characteristics of a stomach

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which could still be considered “normal.” Regarding the use of the word, “substantially,” while the Applicant has indicated that the MPEP provides guidance for the word, “substantially,” the Examiner does not find this argument persuasive because it is unclear what metes and bounds are encompassed by “substantially,” especially when considered in light of “substantially” being used to describe “normal.” As such, claim 1 remains rejected. Claims 2-8 depend on claim 1.

Applicant's arguments, see page 13-14, filed June 28, 2004, with respect to claim 1 being rejected for lacking antecedent basis by using the phrases, “said surgical modification” and “said intestinal tract,” have been fully considered and are persuasive. Applicant has amended the claims. The rejection of claim 1 has been withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 7, 8 remain rejected under 35 U.S.C. 102(b) as being anticipated by Young et al., 1984, The American Journal of Clinical Nutrition, 40: 293-302, previously cited, for reasons of record, March 14, 2005.

Applicant's arguments filed June 28, 2005, pages 14-17, have been fully considered but they are not persuasive.

The Applicant indicates that Young et al. do not anticipate the claimed invention because Young et al. teach the elimination of the stomach as an organ of digestion and that a functioning stomach is the source of ghrelin production, and thus, a reduction in ghrelin levels in post-operative rats could not be inherent in Young et al. (Applicant's response, page 17). While the Applicant provides this assertion, the Applicant provides no guidance (e.g. evidence) that Young et al. teach an entirely different method of bariatric surgery which leads to an increase in ghrelin levels in the surgically modified nonhuman mammalian model. It is noted that bariatric surgery would subsequently reduce levels of ghrelin in the animal model, regardless of whether Young et al. were actually aware that ghrelin levels were changing following surgery and no guidance was provided contrary to this situation. It is noted that there appears to be no difference in parameters used by Young et al. to indicate that the animals would have different levels of ghrelin, or that in fact, the animals taught by Young et al. were prepared similarly and have different levels of ghrelin than that of the claimed invention. In addition to this issue, the Applicant indicates on page 17, 1<sup>st</sup> parag., that "Young et al. teach the elimination of the stomach as an organ of digestion, and since a functioning stomach is the very source of ghrelin production, (and) a reduction in ghrelin levels in post-operative rats could not possibly be inherent in Young, et al." With regards to this argument, it appears that the Applicant is supporting the Examiner's assertion that the levels of ghrelin in the rats taught by Young et al. would go down because these rats, which have no functional stomach (i.e., the stomach was eliminated), would also not



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express ghrelin. As such, Young et al. anticipate the claimed invention and the rejection remains.

### ***Conclusion***

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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JH

  
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